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RPP:135F US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Molly F. Kulesz-Martin Art Unit: 1642

Serial No: 08/811,361

Filed: March 4, 1997

Examiner: Geetha P. Bansal

For: p53as PROTEIN AND ANTIBODY THEREFOR

I certify that this Reply Brief is being deposited on March 1, 1999 with the U.S. Postal Service as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

Michael L. Dunn
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REPLY BRIEF

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in reply to the Examiner's Answer dated January 4, 1999.

In his answer, the Examiner raised a number of arguments for the first time.

"Secondly, Appellant asserts that the C terminal should have a unique epitope. Without knowing what constitutes the sequence making up the epitope, it is not possible to determine if a series of amino acids making up the epitope in the C terminal peptide is not also present in the body of the p53 or p53as molecule."

The Examiner continues to miss the point of the invention. p53 and p53as are essentially identical except proximate the carboxy terminal region. p53 and p53as both function as growth regulators in essentially the same way. The difference between p53 and p53as is that p53 has a negative regulatory domain at its carboxy terminal end that can "turn off" its regulatory function. p53as lacks that regulatory function and is thus always active. An always active

p53as can be obtained by simply truncating p53 to remove the negative regulatory domain. See Hupp et al. discussed on page 2 of the specification. An "always active" truncated p53 give rise to problems for a researcher. In particular, it cannot be detected in the presence of p53 since all of its sequences are also present in p53. This problem can be cured by attaching a unique epitope to the end of a truncated p53 to make a p53as that is detectable in the presence of p53. Essentially any unique epitope will do, as long as it is not the "originally removed" negative regulatory domain. The added epitope usually does not adversely affect the activity of the p53as because that portion of p53as responsible for its activity is not disturbed. Such a p53as with a unique epitope not present in p53 may occur naturally or be synthesized. There is complete enablement in the specification for isolation of "wild type" i.e., natural p53as and for identification of its unique C terminus epitope of the peptide presently claimed. There is enablement since the procedures described in the specification can be applied to any animal, and there is no ambiguity. It is clear from the specification that "unique epitope" means an epitope not present in p53. Since the sequence of p53 is known, uniqueness is easy to determine. The rejections under 35 USC 112 should be reversed.

Once the foregoing is understood, it is clear that Arai et al. does not each or suggest the present invention. Arai et al. never isolated any protein, but predicated a protein sequence from a nucleotide sequence. Further, the nucleotide sequence used by Arai et al. is not a p53 based material, e.g., it transforms cells rather than suppressing transformation and growth as does p53 and it forms monomers and dimers, not tetramers as does p53. Further, there is no suggestion or teaching in Arai et al. that any particular peptide sequence within the Arai et al. "predicted"

protein should be isolated for any purpose whatsoever. This is in contrast to the present claims to a particular isolated peptide.

Respectfully submitted,

Dated: March 1, 1999

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AF/1642

TRANSMITTAL LETTER Applicant(s): Molly F. Kulesz-Martin			Attorney Docket No: RPP:135F-US #15
Serial No: 08/811,361	Filing Date: March 4, 1997	Examiner: Geetha P. Bansal	Art Unit: 1642
Invention: p53as PROTEIN AND ANTIBODY THEREFOR			

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

Transmitted herewith is a/an: REPLY BRIEF (in triplicate)

IN THE ABOVE IDENTIFIED APPLICATION.

[X] No additional fee is required.

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A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Dated: March 1, 1999

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